

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

IN RE YASMIN AND YAZ (DROSPIRENONE)
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

3:09-md-02100-DRH-PMF

MDL No. 2100
ORDER

This Document Relates to:

Evangeline Semark Lemoine,

Plaintiff,

Case No. 3:10-cv-20332-DRH-PMF

v.

**TEVA PHARMACEUTICAL
INDUSTRIES, LTD., TEVA
PHARMACEUTICALS USA,
INC., BAYER CORPORATION,
BAYER HEALTHCARE
PHARMACEUTICALS, INC.,
BAYER HEALTHCARE, LLC,
BAYER SCHERING
PHARMA AG, BAYER HEALTHCARE AG
and WALGREEN CO.**

Defendants

ORDER

HERNDON, Chief Judge:

I. INTRODUCTION

This case was originally filed in the Circuit Court of Cook County, Illinois. On January 19, 2010, Defendants Bayer Corporation, Bayer HealthCare Pharmaceuticals Inc. and Bayer HealthCare LLC (collectively, "Removing

Defendants”) removed this action to the Northern District of Illinois based on diversity of citizenship pursuant to 28 U.S.C. § 1332 and alleging that the sole non-diverse Defendant, Walgreen Co. (“Walgreen”), had been fraudulently joined (Doc. 1). Plaintiff in turn moved for remand to state court (Doc. 30). In an order issued contemporaneously herewith, the Court denied Plaintiff’s motion for remand, finding that Defendant Walgreen had been fraudulently joined.

Plaintiff’s claims arise from personal injuries suffered as an alleged result of the prescription pharmaceutical product Ocella, a generic version of the oral contraceptive Yasmin (Doc. 1 pp. 30-32 ¶¶ 61-68; Doc. 5 ¶ 33). Plaintiff asserts claims against TEVA Pharmaceutical Industries, LTD., TEVA Pharmaceuticals USA, INC. (collectively, “TEVA Defendants”), Bayer Corporation, Bayer HealthCare Pharmaceuticals Inc., Bayer HealthCare, LLC, Bayer Schering Pharma AG, Bayer HealthCare AG (collectively, “Bayer Defendants”), and Walgreen. Plaintiff’s claims against Walgreen (strict liability, negligence, and breach of implied warranty of merchantability) are based on its alleged status as the pharmacy that filled her prescription for Ocella. Plaintiff does not allege that Walgreen mistakenly filled or mislabeled her prescription, gave her the wrong dosage, or did anything other than fill her prescription pursuant to her physician’s instructions.

Now before the Court is Walgreen’s motion to dismiss the claims directed against it pursuant to Federal Rule of Civil Procedure 12(b)(6) (Doc. 34). For the reasons stated herein, the motion is **GRANTED**.

II. ANALYSIS

A. Legal Standard

A motion to dismiss under Rule 12(b)(6) challenges a complaint for failure to state a claim upon which relief may be granted. **See Fed.R.Civ.P. 12(b)(6); Gen. Elec. Capital Corp. v. Lease Resolution Corp., 128 F.3d 1074, 1080 (7th Cir.1997)**. In reviewing a motion to dismiss, the Court takes as true all factual allegations in Plaintiff's complaint and draws all reasonable inferences in Plaintiff's favor. **Killingsworth v. HSBC Bank Nevada, N.A., 507 F.3d 614, 618 7th Cir.2007**).

B. Plaintiff's Claims

Plaintiff brings three counts against Walgreen: (1) strict liability; (2) negligence; and (3) breach of implied warranty (Doc. 1 pp. 48-51 ¶¶ 151-167). . . As these are state law claims, Illinois substantive law applies. **See Erie R. Co. v. Tompkins, 304 U.S. 64, 78 (1938)**. The Court addresses each Count below.

C. Analysis of Strict Liability and Negligence Claims

1. Pharmacist duty to warn

The viability of the strict liability and negligence counts depend on whether Illinois imposes an affirmative duty on pharmacists to warn customers about a drug's risks and side effects. Accordingly, resolution of these counts depends on whether Walgreen owed Plaintiff a duty to warn.

As a preliminary matter, this Court notes that the issue before it is a narrow one. Plaintiff is not alleging that Walgreen incorrectly filled her

prescription or that Walgreen negligently performed a voluntary undertaking. Nor is Plaintiff alleging that Walgreen had patient-specific knowledge about her drug allergies and therefore knew the prescribed drug was contraindicated for her. In each of these scenarios, Plaintiff would have a valid claim against Walgreen under Illinois law. **See Jones v. Walgreen Co., 265 Ill. App. 308 (Ill. App. 1932) (when doubt exists as to what drug has been prescribed, pharmacist has a duty to take reasonable precautions to ensure prescription is accurately filled); Frye v. Medicare-Glaser Corp., 605 N.E.2d 557 (where pharmacy voluntarily provides warning about prescription drug to customer, the extent of pharmacy's duty is to perform the voluntary undertaking without negligence); Happel v. Wal-Mart Stores, Inc., 766 N.E.2d 1118, 1129 (Ill. 2002) (pharmacy has "narrow duty to warn" when it has "patient-specific information about drug allergies, and knows that the drug being prescribed is contraindicated for the individual patient").** Rather, Plaintiff's failure to warn claims assert that Walgreen is liable, in both strict liability and negligence, for distributing a prescription drug that allegedly contained inadequate warnings. Accordingly, the limited question before the Court is whether, under Illinois law, a pharmacist, that correctly fills a prescription and does not have any patient-specific knowledge, has an affirmative duty to warn a customer about a prescription drug's potential side effects.

Illinois courts have consistently held that a pharmacist does not have an affirmative duty to provide customers with a warning regarding a drug's

potential risks or side effects. **See *Happel*, 766 N.E.2d at 1129 (absent an allegation of “specialized knowledge,” pharmacies have no affirmative duty to warn patients of potential adverse reactions to prescription drugs); *Leesley v. West*, 518 N.E.2d 758 (Ill. App. Ct. 1988) (pharmacists have no duty to provide patients with a written copy of a prescription drug’s known risks and side effects); *Jones v. Irvin*, 602 F. Supp. 399, 401 (S.D. Ill. 1985) (“the overwhelming majority of recent state cases stand for the proposition that the pharmacist has no duty to warn”).**

One of the stated reasons for declining to impose a duty to warn on pharmacists is that imposing such a duty would run contrary to the public policy against “expanding the liability risks of health professionals.” ***Leesley*, 518 N.E.2d at 763.** Additional reasons cited by Illinois courts include: (1) Interference with the doctor-patient relationship ***see e.g., Fakhouri*, 618 N.E.2d at 521**; (2) the magnitude of the burden of imposing a duty to warn is too great ***see Leesley*, 518 N.E.2d at 763**; (3) the injury that might result due to the absence of a particular warning is not reasonably foreseeable ***see Id.***; and (4) imposing a duty to warn would be inconsistent with the learned intermediary doctrine.¹ ***See Id.* at 762-763 (declining to impose a duty to warn on the**

¹ The learned intermediary doctrine provides that pharmaceutical manufacturers do not have a duty to directly warn patients about a prescription drug’s dangerous propensities. Rather, pharmaceutical manufacturers have a duty to inform physicians of the dangers of prescription drugs, and that physicians have a duty to warn patients of those dangers. ***See Kirk v. Michael Reese Hospital and***

defendant pharmacy, in part, because it would be “illogical and inequitable” to impose a duty on a pharmacist that is not imposed on the drug’s manufacturer). Considering these opinions, it is clear that in Illinois, a pharmacist does not have an affirmative duty to warn customers about a prescription drug’s dangerous propensities or side effects.

As an additional matter, the Court addresses the parties’ arguments with respect to the learned intermediary doctrine. Plaintiff contends that Walgreen’s duty to warn is a question of fact that must be resolved by a jury because (1) the adequacy of the warnings provided by the manufacturing defendants is in question; (2) the adequacy of the subject warnings is a question of fact for the jury; and (3) Walgreen’s liability is dependent on whether the manufacturing defendants provided adequate warnings. The Court agrees that the adequacy of warnings is generally a question of fact for the jury. The Court, however, does not agree that a pharmacy is shielded from liability for failure to warn if and only if the manufacturing defendant has provided the prescribing physicians with adequate warnings.²

Illinois Courts have consistently held, absent certain exceptions not present here, that a pharmacist does not have an affirmative duty to warn. The

***Medical Center*, 513 N.E.2d 387, 392 (Ill. 1987) (considering a drug manufacturer’s duty to warn and adopting the learned intermediary doctrine).**

² The Court is familiar with the line of cases out of the Southern District of Illinois that have adopted Plaintiff’s line of reasoning. ***See e.g., McNichols v. Johnson & Johnson*, 461 F. Supp. 2d 736 (S.D. Ill. 2006) (Murphy, P.)**. These cases, however, are not binding on this Court and for the reasons discussed above the Court declines to adopt this reasoning.

learned intermediary rule is one reason Illinois courts have cited in support of declining to impose such a duty. The relevant authority, however, does not indicate that whether a pharmacist owes such a duty is dependent on the adequacy of a manufacturer's warning in a particular case. Moreover, adopting Plaintiff's proposed reasoning would nullify the no duty to warn rule and would be contrary to the policy considerations that have been relied on in declining to impose such a duty.

2. Dismissal of strict liability claim under 735 ILCS 5/2-621

Walgreen asserts that it is entitled to dismissal of Plaintiff's strict liability claim because it has complied with the requirements of section 2-621 of the Illinois Code of Civil Procedure. (Doc. 35 p. 14).³ Section 5/2-621 authorizes dismissal of a nonmanufacturing defendant in a product liability case once the manufacturer has been identified and made part of the litigation. Plaintiff has sued Bayer Scherring Pharma AG. Bayer Scherring Pharma AG admits that "it manufactures drospirenone and ethinyl estradiol, the progestin and estrogen contained in YAZ, Yasmin and Ocella." (MDL 2100 Doc. 669, p. 5). Accordingly, the Court finds that, in addition to the reasons already discussed, Walgreen is entitled to dismissal of the strict liability claim pursuant to Section 2-621.

³ Although § 2-621 can be viewed as procedural, the courts, in fact, view it as substantive for the purposes of *Erie*. See e.g., *LaRoe v. Cassens & Sons, Inc.*, 472 F. Supp. 2d 1041, 1047 (S.D. Ill. 2006).

3. Dismissal for failure to comply with 735 ILCS 5/2-622

Walgreen also argues that Plaintiff's claims are healing arts malpractice claims and subject to the certification requirements of the Healing Arts Malpractice Act ("HAMA") (Doc. 35 pp. 2-5).³ **735 ILCS 5/2-622**. Plaintiff's reply memorandum does not address this argument.

Illinois courts have not expressly addressed whether claims brought against a pharmacist fall under HAMA. The term "healing arts" is broad in its scope and concerns issues of medical judgment. ***Childs v. Pinnacle Health Care, LLC*, 399 Ill. App. 3d 167, 182 (2nd Dist. 2010)**. It is not limited to health professionals. ***Lyon v. Hasbro Industries, Inc.*, 156 Ill. App. 3d 649, 654, 109 Ill. Dec. 41, 509 N.E.2d 702, 706 (4th Dist. 1987) citing *Bernier v. Burris*, 113 Ill. 2d 219, 100 Ill. Dec. 585, 497 N.E.2d 763 (1986)**. Rather, "It encompasses 'the entire branch of learning dealing with the restoration of physical or mental health.'" ***Childs*, 399 Ill. App. 3d at 182 (2nd Dist. 2010)**. The term "Malpractice" is defined generally as "[a]n instance of negligence or incompetence on the part of a professional." ***Id. citing Black's Law Dictionary 971 (7th ed. 1999)***. Considering the above, the term healing arts malpractice seems to include tortious claims directed against a pharmacist which call into question the pharmacist's professional judgment.

³Section 5/2-622 mandates that any healing arts malpractice actions must include a health professional report and attorney affidavit. **735 ILCS 5/2-622(a)**. Failure to comply with this requirement is grounds for dismissal. **735 ILCS 5/2-622(g)**.

Although not binding on this Court, the Court notes that the Northern District of Illinois reached a similar conclusion in ***Happel v. Wal-Mart Stores, Inc.***, 286 F. Supp. 2d 943, 946-947 (N.D. Ill. 2003) (Moran, J.). In ***Happel***, the district court first noted that generally, “pharmacists filling prescriptions are shielded from negligence actions under the rationale that pharmacists should not be responsible for the choices made by prescribing physicians, without having a physician's knowledge of each patient.” ***Id.* at 946.** The plaintiff's negligence claims, however, were premised on the proposition that under certain circumstances a pharmacist owes a duty to warn patients of a prescriptions contraindications. ***Id.* at 947.** Recognizing this duty to warn as an exception to the general rule, the district court concluded that “a negligence claim which “relies on the proposition that [a pharmacy] had a duty to warn [plaintiffs] of a prescriptions contraindications” is a healing art malpractice claim because the imposition of such a duty requires pharmacies to “play a more active role in the prescription process” and entitles pharmacies to the protections found in the Healing Arts Malpractice Act.

The Court concludes that HAMA would apply to a viable failure to warn claim brought against a pharmacy. Thus, if Plaintiff's complaint included viable failure to warn claims directed against Walgreen, those claims would be subject to dismissal for failure to comply with the certification requirements of HAMA. In the instant case, however, Plaintiff has not brought a viable failure to warn claim against Walgreen. Plaintiff has not alleged, for instance, that Walgreen

had patient specific knowledge and failed to warn of a known contraindication (circumstances under which a duty to warn would be imposed). Rather, Plaintiff's strict liability and negligence claims rely on the proposition that pharmacists owe a general affirmative duty to warn. For the reasons discussed above, the Court finds that no such duty exists.

D. Analysis of Breach of Implied Warranty of Merchantability Claim

Plaintiff asserts a claim for breach of implied warranty of merchantability against Walgreen based on its role as the pharmacy that allegedly dispensed Ocella to the Plaintiff (Doc. 1 pp. 50-51 ¶¶ 161-167). Breach of warranty claims only apply to transactions in goods as defined by the Illinois Commercial Code ("ICC"). **See 810 ILCS 5/2-102.** The ICC defines goods as "all things, including specially manufactured goods, which are movable at the time of identification to the contract for sale." **810 ILCS 5/2-105(1).** Prescription medication, such as Ocella, would constitute a good under this definition.

The practice of pharmacy, however, involves more than the provision of pharmaceuticals; it also involves the provision of professional healthcare services. **See e.g., 225 ILCS 85/3(d)(1) ("practice of pharmacy" includes "the interpretation and the provision of assistance in the monitoring, evaluation, and implementation of prescription drug orders"); 225 ILCS 85/3(d)(4) ("practice of pharmacy" includes "patient education on the proper use or delivery of medications"); 225 ILCS 85/3(d)(7) ("practice of pharmacy" includes the "provision of patient counseling"); 225 ILCS 85/3(r)(3) ("patient**

counseling” includes “facilitation of the patient's understanding of the intended use of the medication”); 225 ILCS 85/3(d)(9) (“practice of pharmacy” includes “the provision of those acts or services necessary to provide pharmacist care”); 225 ILCS 85/3(d)(10) (“practice of pharmacy” includes “medication therapy management”); ILCS 85/3(d); 225 ILCS 85/1 (the practice of pharmacy in Illinois is “a professional practice affecting the public health, safety and welfare”). See also *Walgreen Co. v. Selcke*, 230 Ill. App. 3d 442, 451 (Ill. App. 1992) (acknowledging that the practice of pharmacy involves more than pulling packages from a shelf and ringing up a sale; the practice of pharmacy involves “the exercise of pharmaceutical interpretation, skill or knowledge of medicine or drugs. The pharmacist chooses and describes the desired ingredient, as prescribed by the physician, and [makes determinations] from his or her own knowledge, training and experience”).⁴

Accordingly, a transaction such as the one at issue in this case, is a mixed transaction involving both the provision of goods and the provision of services. In Illinois, where a transaction involves both the provision of goods and services, courts apply the “predominant purpose test” to determine whether there has been a transaction in goods. Pursuant to the predominant purpose test,

⁴ Plaintiff's brief in reply seems to acknowledge that the practice of pharmacy involves more than just the provision of goods (*See Doc. 37 pp. 2-4*) (noting a pharmacist's “education requirements” and arguing that (1) a pharmacist is a “chemist” with knowledge about the ingredients in prescription drugs; (2) pharmacists don't “merely” fill prescriptions but are “chemically trained” and possess knowledge regarding the drugs they are dispensing).

“there is a ‘transaction in goods’ only if the contract is predominantly for goods and incidentally for services.” **Brandt v. Boston Scientific Corp.**, 204 Ill.2d 640, 275 Ill.Dec. 65, 792 N.E.2d 296 (Ill.2003) citing **Belleville Toyota, Inc. v. Toyota Motor Sales, U.S.A., Inc.**, 199 Ill.2d 325, 352-353, 264 Ill. Dec. 283, 770 N.E.2d 177 (2002).

The Illinois Supreme Court applied the predominant purpose test to an analogous transaction in **Brandt v. Boston Scientific Corp.**, 204 Ill.2d 640, 275 Ill.Dec. 65, 792 N.E.2d 296 (Ill.2003).⁵ The transaction at issue in **Brandt**, involved the sale of a medical device, by a health center, in conjunction with the provision of other healthcare services. The court concluded that although the transaction included the sale of a medical device, the “predominate nature of the transaction as a whole” was the provision of medical treatment for the plaintiff’s infection and thus, the transaction was primarily one for services. **Id. at 652-653**. In so holding, the court noted that the plaintiff did not come to the health center “merely to buy a [medical device] as one buys goods from a store.” Rather, the plaintiff came to the health care center to receive treatment for her condition and the treatment she received involved a number of services in addition to the provision of the medical device.

⁵ Before applying the predominant purpose test, the court examined and declined to follow **Cunningham v. MacNeal Memorial Hospital**, 47 Ill.2d 443, 266 N.E.2d 897 (1970). The Court explained that **Cunningham** was not applicable because, among other things, the decision was issued prior to the adoption of the predominant purpose test. The Court also noted that the **Cunningham** rationale was applied in **Berry v. G.D. Searle & Co.**, 56 Ill.2d 548, 554-55, 309 N.E.2d 550 (1974). Accordingly, **Cunningham** and **Berry** are not applicable to the breach of warranty analysis in this case.

The transaction at issue in the instant case is analogous to the transaction at issue in **Brandt**. In the instant case, the sale of Ocella was just one aspect of the transaction between Walgreen and the Plaintiff. Prescription drugs are not available to the general public. They can only be legally distributed pursuant to a valid prescription from a licensed physician. **See 21 U.S.C. § 353(b); 410 ILCS 620/2.37; 410 ILCS 620/3.21.** A pharmacist acts as the gate-keeper of prescription medication, monitoring the distribution and implementation of prescription drug orders. Thus, a pharmacist provides a service to the patient, the physician, and the community. Moreover, the pharmacist provides a number of professional healthcare services, including utilizing professional skill and care to interpret and evaluate the prescription; educating patients as to the intended use of the medication and manner of ingestion; and maintaining necessary records for compounding, labeling, and storing pharmaceuticals.

Considering the entirety of the transaction, as the Illinois Supreme Court did in **Brandt**, it is evident that the sale of pharmaceuticals is just one aspect of the transaction between patient and pharmacist. The predominant purpose of such transactions is the provision of professional healthcare services which are a necessary step in completing the treatment regimen selected by the patient's physician. Therefore, the subject transaction was not a "transaction in goods" and Plaintiff's breach of warranty claim has no reasonable chance of success.

In addition, as the Court has already discussed, in Illinois, pharmacies and pharmacists are immune from failure to warn claims. Allowing plaintiffs to pursue a breach of warranty claim against pharmacists would nullify this protection and would be inconsistent with the policy against “expanding the liability risks of health professionals.” *Id.* at 763. *See also Id.* at 763.

Finally, the Court notes a recent decision from the Illinois Supreme Court, *De Bouse v. Bayer AG*, 235 Ill. 2d 544 (2009) (“*De Bouse*”). In *De Bouse*, a product liability action involving the prescription drug Baycol, the Illinois Supreme Court considered prescription drugs in the context of the “unavoidably unsafe” exception to the general rule of strict liability found in the Restatement (Second) of Torts § 402A, Comment K (“Comment K”). *Id.* at 557-558. As the Illinois Supreme Court explained, Comment K “reflects the reality that even in their intended and ordinary use, prescription drugs may nonetheless cause harmful side effects in some patients.” *Id.* at 558. Considering the risks associated with pharmaceuticals and the exception found in Comment K, the court concluded that the mere sale of a prescription medication does not constitute a representation that the drug will be reasonably safe for its intended use. *Id.*

The Court notes this decision and its conclusions with regard to the nature of prescription drugs because Illinois courts have found that causes of action for breach of implied warranty of merchantability and strict liability in tort are nearly identical. *See Alvarez v. American Isuzu Motors*, 321 Ill. App. 3d

696, (1st Dist. 2001) (concepts are “nearly identical”); *Garcia v. Edgewater Hosp.*, 244 Ill. App. 3d 894 (1st Dist. 1993) (claim for tort of strict products liability is essentially a claim for breach of implied warranty of merchantability), *overruled in part on other grounds by Brandt v. Boston Scientific Corp.*, 204 Ill. 2d 640 (2003); *State Farm Fire and Cas. Co. v. Miller Elec. Co., a Div. of Carol Cable Co., Inc.*, 204 Ill. App. 3d 52, 61 (2nd Dist. 1990). In strict liability actions, the concept of “reasonable safety” is used for assessing whether a product is defective. This concept parallels and, according to some authorities,⁶ is co-extensive with the implied warranty concept of merchantability. Accordingly, the **Du Bois** decision may support the conclusion that the mere sale of a prescription drug cannot be the basis for a breach of implied warranty of merchantability claim. The Court, however, merely notes this possibility. Although Illinois courts have recognized the significant overlap between causes of action for breach of implied warranty of merchantability and strict product liability, Illinois courts have not expressly stated that the concepts of merchantability and reasonable safety are coextensive.⁷

⁶ See e.g., Comment 7 to the Uniform Commercial Code § 2-314 (2003) (stating that the concepts are coextensive). See also *Id.* (as to the questions “if goods are merchantable under warranty law, can they still be defective under tort law, and if goods are not defective under tort law, can they be unmerchantable under warranty law? The answer to both questions should be no.”); *Id.* (“When recovery is sought for injury to person or property, whether goods are merchantable is to be determined by applicable state products liability law.”). Illinois, however, has not codified this comment. See 810 ILCS 5/2-314.

⁷ In addition, as noted, Illinois has not codified U.C.C. § 2-314 Cmt. 7 (2003). See 810 ILCS 5/2-314.

III. CONCLUSION

For the foregoing reasons, the Court **GRANTS** Walgreen's motion to dismiss. (Doc. 34).

SO ORDERED:

  David R. Herndon
2010.11.24 15:14:17
-06'00'

Chief Judge
United States District

Date: November 24, 2010